

REMARKS

Applicants respectfully request reconsideration and reexamination of the present application in light of the amendments and the remarks below.

Claims 1, 6, and 16 are pending in this application. Applicants elected Group I, claims 1 and 6-19 drawn to a polypeptide and pharmaceutical compositions (Response A mailed May 31, 2002). Claims 2-5 and 20-31 were cancelled (Response A mailed May 31, 2002). In addition, Applicants elected SEQ ID NO: 72 for further prosecution, and Claims 7-15 and 17-19 were cancelled (Response B mailed July 10, 2002).

Specification

The Examiner requested that a substitute specification be filed with sufficient space at the top of the pages for hole-punching (Paper No. 12, page 2).

A substitute specification has been provided as requested by the Examiner (37 C.F.R. 1.125(a)). The substitute specification includes no new matter.

Sequence Rules Compliance

The Examiner stated that pages 6 and 13, lines 33 and 19, respectively, of the specification disclose sequences which are not identified by SEQ ID NOs (Paper No. 12, pages 2-3).

The specification has been amended to include the SEQ ID NOs. In addition, an amended sequence listing has also been submitted. A copy of the amended sequence listing has been provided for the Examiner.

Rejection Under 35 U.S.C. § 102

The Examiner rejected claims 1, 6, and 16 under 35 U.S.C. § 102(b) as being anticipated by Bolin (U.S. Patent No. 5,234,907) (Paper No. 12, pages 3-4). Applicants respectfully traverse this rejection.

In order to support anticipation under 35 U.S.C. § 102, each and every element of a claimed invention must be disclosed within a single prior art reference. *See In re Bond*, 15 USPQ2d 1896 (Fed. Cir. 1991).

The Examiner stated that Bolin teaches a variety of proteins (SEQ ID NOs: 1-93 of the sequence listing) which are variants of instant SEQ ID NO: 72. Since all of Bolin's peptides are variants of VIP, as instant SEQ ID NO: 72, and Bolin teaches that his peptides have similar function (col. 8, lines 63-68), claims 1 and 16 are anticipated. Bolin also teaches that his peptides may be combined with pharmaceutical carriers (col. 9, lines 1-4), thus anticipating claim 6 (Paper No. 12, pages 3-4).

The present invention relates to a polypeptide of SEQ ID NO: 72, and functionally equivalent fragments, derivatives, and variants; and a pharmaceutical composition comprising the polypeptide of SEQ ID NO: 72. Furthermore, the polypeptide of the present invention is a selective pituitary adenylate cyclase activating peptide (PACAP) receptor 3 (R3) agonists.

Bolin discloses vasoactive intestinal peptide (VIP) analogs; however, Bolin does not teach or disclose the polypeptide of the present invention. Bolin also does not teach or disclose polypeptides that are selective R3 agonists. For example, Bolin does not teach or disclose a polypeptide in which the amino acid at position 24 has been mutated to glutamine (Gln or Q), the amino acid at position 28 has been mutated to asparagine (Asn or N), the amino acid at position 29 has been mutated to lysine (Lys or K), the amino acid at position 30 has been mutated to arginine (Arg or R), and the amino acid at position 31 has been mutated to tyrosine (Tyr or Y).

As defined in the specification, the terms “fragments,” “derivatives,” and “variants” refer to fragments, derivatives, and variants which retain substantially the same biological function or activity as the polypeptide of the present invention. The polypeptide of the present invention, as mentioned above, is a selective R3 agonist. Thus, fragments, derivatives, and variants of this polypeptide would retain the same biological function, that is, a selective R3 agonist. The peptides disclosed by Bolin possess VIP activity (*see, e.g.*, Examples 97 and 98 of the specification of U.S. Patent No. 5,234,907). Therefore, Bolin does not teach or disclose the polypeptide of SEQ ID NO: 72, and functionally equivalent fragments, derivatives, and variants; and a pharmaceutical composition comprising the polypeptide of SEQ ID NO: 72.

Since Bolin, does not teach each and every limitation of the claimed invention, a proper rejection under 35 U.S.C. § 102(b) has not been established. Accordingly, Applicants respectfully request reconsideration and withdrawal of the of the present rejection.

The Examiner also rejected claims 1, 6, and 16 under 35 U.S.C. § 102(b) as being anticipated by Sawai, et al. (U.S. Patent No. 5,376,637) (Paper No. 12, page 4). Applicants respectfully traverse this rejection.

The Examiner stated that Sawai teaches pharmaceutical compositions comprising peptides which are variants of instant SEQ ID NO: 72. Since Sawai's peptides are variants of VIP, as is instant SEQ ID NO: 72, and Sawai teaches that his peptides have similar function, claims 1, 6, and 16 are anticipated (Paper No. 12, page 4).

Sawai, et al., disclose vasoactive intestinal peptide (VIP) analogues; however, Sawai, et al., do not teach or disclose the polypeptide of the present invention. Sawai, et al., also do not teach or disclose polypeptides that are selective R3 agonists. Specifically, Sawai, et al., disclose analogues in which the

amino acid at position 17 of the native VIP (28 amino acids) has been mutated. Sawai, et al., do not teach or disclose the polypeptide of SEQ ID NO: 72 (31 amino acids).

Furthermore, the analogues disclosed by Sawai, et al., possess VIP activity (*see, e.g.*, Examples 1-3 of the specification of U.S. Patent No. 5,376,637), not selective R3 agonist activity. As discussed above, fragments, derivatives, and variants of the polypeptide of the present invention would retain activity as a selective R3 agonist. Therefore, Sawai, et al., does not teach or disclose the polypeptide of SEQ ID NO: 72, and functionally equivalent fragments, derivatives, and variants; and a pharmaceutical composition comprising the polypeptide of SEQ ID NO: 72.

Since Sawai, et al., does not teach each and every limitation of the claimed invention, a proper rejection under 35 U.S.C. § 102(b) has not been established. Accordingly, Applicants respectfully request reconsideration and withdrawal of the of the present rejection.

CONCLUSION

For the foregoing reasons, Applicants submit that the claims are in condition for allowance and Applicants respectfully request reexamination of the present application, reconsideration and withdrawal of the present rejections, and entry of the amendments. Should there be any further matter requiring consideration, Examiner Moran is invited to contact the undersigned counsel.

If there are any further fees due in connection with the filing of the present reply, please charge the fees to undersigned's Deposit Account No. 13-3372. If a fee is required for an extension of time not accounted for, such an extension is requested and the fee should also be charged to undersigned's deposit account.

Respectfully submitted,


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